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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,839	03/07/2001	Toshihiro Shimizu	2535US1P	7614
23115	7590	07/21/2004	EXAMINER	
TAKEDA PHARMACEUTICALS NORTH AMERICA, INC			TRAN, SUSAN T	
INTELLECTUAL PROPERTY DEPARTMENT			ART UNIT	
475 HALF DAY ROAD			PAPER NUMBER	
SUITE 500			1615	
LINCOLNSHIRE, IL 60069			DATE MAILED: 07/21/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/800,839	SHIMIZU ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7,9-11 and 13-24 is/are pending in the application.
- 4a) Of the above claim(s) 22-24 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-11 is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7 and 13-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt is acknowledged of applicant's Amendment and Extension of Time filed 04/21/04.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-7, and 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundberg US 6,132,770.

Lundberg teaches an effervescent tablet comprising mixture proton pump inhibitor (ppi) core (acid-labile active substance) and filler, binder, lubricant, disintegrant, surfactant, other additives, and alkaline reacting agent (basic salt), including, calcium and magnesium salts (column 8, lines 55 through column 9, lines 1-5). Lundberg also teaches that the tablet having disintegrating time of about 55 seconds (see examples).

Lundberg is silent as to the teaching of the percent hydroxypropoxyl group, however, it is noted that Lundberg teaches a similar disintegration time using the hydroxypropyl cellulose in his effervescent tablet (see examples). Accordingly, it is the position of the examiner that Lundberg teaches the use of at least similar hydroxypropyl cellulose having the claimed hydroxypropoxyl group. Therefore, the burden is shifted to applicant to present data showing that the hydroxypropyl cellulose taught by Lundberg

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is different in nature. Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine a suitable hydroxypropyl cellulose to obtain the claimed invention, because Lundberg teaches the use of hydroxypropyl cellulose in an effervescent tablet (rapidly disintegrable solid dosage form) to achieve a desirable rapid disintegration time.

Response to Arguments

Applicant's arguments filed 04/21/04 have been fully considered but they are not persuasive.

Applicant argues that Lundberg, by contrast with the claimed invention teaches a multiple unit effervescent tablets that is dissolved and/or dispersed in an aqueous medium, such as drinking water. Contrary to the applicant's argument, the effervescent tablet taught by Lundberg is suitable for oral use (see column 1, lines 13-14). Nothing in Lundberg prevent a patient from administering the effervescent tablet my mouth, and nothing in Lundberg indicating that the effervescent tablet will not disintegrate in a patient mouth, which also known to be an aqueous medium environment. Applicant's attention is called to column 3, lines 53-55, where Lundberg also recognizes the advantageous results desired by the applicant, namely, and effervescent dosage form suitable for patients with swallowing disorders and in pediatrics.

Applicant argues that Lundberg does not teach the buccal disintegration time. Contrary to the applicant's argument, Lundberg teaches a dosage form that dispersed or disintegrated rapidly in aqueous medium. Additionally, Lundberg also teaches

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disintegration time of about 55 seconds (see examples), which falls in the claimed range. Accordingly, the burden is shifted to applicant to submit data showing that the effervescent dosage form of Lundberg does not exhibit the buccal disintegration time being claimed.

Applicant argues that Lundberg teaches away from the present invention because the tablet of Lundberg dissolved in a glass of water, not in a patients' mouth. Contrary to the applicant's argument, the suggestion that the effervescent tablet of Lundberg is dissolved in water is exemplary evident by the phrase "aqueous medium, *such as*" (column 1, line 65). As discussed above, saliva is also known in pharmaceutical art as an aqueous medium/environment. In any event, the burden is shifted to applicant to establish that the effervescent composition of Lundberg does not disintegrate in a patients' mouth.

Claims Allowable

Claims 9-11 are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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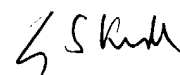
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


S. Tran, PhD
Primary Examiner
Group 1600
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